**FOOD AND DRUG ADMINISTRATION (FDA)**
Center for Drug Evaluation and Research (CDER)

***Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting***
The Marriott Inn and Conference Center, University of Maryland University College (UMUC)
Potomac Ballroom, 3501 University Blvd. East, Hyattsville, Maryland
April 1, 2014

**DRAFT AGENDA**

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*The committee will discuss the efficacy and safety of new drug application (NDA) 022472, Afrezza, (Technosphere Insulin Inhalation System), 3 unit and 6 unit cartridges for oral inhalation, submitted by MannKind Corporation. Afrezza is proposed to improve glycemic control in adult patients with type 1 or type 2 diabetes mellitus.*

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| 8:00 a.m. | Call to Order and Introduction of Committee | **Robert J. Smith, MD**<br>Acting Chairperson, EMDAC |
| 8:10 a.m. | Conflict of Interest Statement | **Karen Abraham-Burrell, PharmD**<br>Designated Federal Officer, EMDAC |
| 8:15 a.m. | FDA Introductory Remarks | **Jean-Marc Guettier, MD**<br>Acting Division Director<br>Division of Metabolism and Endocrinology Products (DMEP)<br>Office of Drug Evaluation II (ODE-II)<br>Office of New Drugs (OND), CDER, FDA |
| 8:35 a.m. | **APPLICANT PRESENTATIONS** | **MannKind Corporation** |
| | Introduction | **John Bedard**<br>Sr. VP, Regulatory Affairs<br>MannKind Corporation |
| | Medical Need | **Janet B. McGill, MD**<br>Professor of Medicine<br>Washington University, School of Medicine |
| | Drug Product and Pharmacology | **Robert Baughman, PharmD, PhD**<br>Sr. VP, Clinical Sciences<br>MannKind Corporation |
| | Clinical Efficacy | **David B. Bregman, MD, PhD**<br>Medical Director, Clinical Development<br>MannKind Corporation |

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**DRAFT AGENDA (cont.)**

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**APPLICANT PRESENTATIONS (CONT.)**

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| | Clinical Safety | **Nikhil Amin, MD**<br>VP, Clinical Development<br>MannKind Corporation |
| | Clinical Safety | **John Gerich, MD**<br>Professor Emeritus<br>University of Rochester, School of Medicine |
| | Closing Remarks | **Robert Baughman, PharmD, PhD** |
| 10:05 a.m. | Clarifying Questions | |
| 10:15 a.m. | **BREAK** | |
| 10:25 a.m. | **FDA PRESENTATIONS** | |
| | Clinical Pharmacology | **Lokesh Jain, PhD**<br>Clinical Pharmacology, Team Leader<br>Division of Clinical Pharmacology II<br>Office of Clinical Pharmacology (OCP)<br>Office of Translational Sciences (OTS)<br>CDER, FDA |
| | Clinical Efficacy | **Lisa Yanoff, MD**<br>Clinical Reviewer<br>DMEP, ODE-II, OND, CDER, FDA |
| | Pulmonary Safety | **Miya Paterniti, MD**<br>Clinical Reviewer<br>Division of Pulmonary, Allergy and Rheumatology Products (DPARP)<br>ODE-II, OND, CDER, FDA |
| | Non-pulmonary Safety | **Lisa Yanoff, MD** |

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**DRAFT AGENDA (cont.)**

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**FDA PRESENTATIONS (CONT.)**

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| Epidemiology and Post-Market Surveillance | **Patricia Bright, MD**<br>Clinical Reviewer<br>Division of Epidemiology II (DEPI-II)<br>Office of Pharmacovigilance and Epidemiology (OPE)<br>Office of Surveillance and Epidemiology (OSE), CDER, FDA |

11:50 a.m. Clarifying Questions

12:00 p.m. **LUNCH**

1:00 p.m. Open Public Hearing

2:00 p.m. Questions to the Committee/Committee Discussion

3:00 p.m. **BREAK**

3:15 p.m. Questions to the Committee/Committee Discussion (cont.)

5:00 p.m. **ADJOURNMENT**